Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2097278	**(X3) Date Survey Completed** 08/29/2018
Name of Provider or Supplier Statlab Mobile	**Street Address, City, State** 19101 Sw 108th Ave Unit 4, Miami, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2017 and 2018, the laboratory had subsequent unsuccessful performance in proficiency testing for the subspecialty of routine chemistry. Refer to D2096. Findings include: Review of the American Proficiency Institute (API) and Medical Laboratory Evaluation (American Society of Internal Medicine) proficiency testing records and the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on August 29, 2018 at 10:00 AM, showed that the laboratory had subsequent unsatisfactory testing scores for the analytes total bilirubin (Tbili) and chloride (CL) for three out of four testing events in 2017 and 2018.

D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory had subsequent unsuccessful participation in proficiency testing in the subspecialty of routine chemistry. Findings include: On August 29, 2018 on or about 10:00 AM the American Proficiency Institute (API) and American Society of Internal Medicine (MLE) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory had unsuccessful proficiency testing scores for three out of four testing events for the analytes of total bilirubin (Tbili) and chloride (Cl) as shown below. Total bilirubin (Tbili) Testing event #1, 2017 Tbili-40% Testing Event #3, 2017 Tbili-0% Testing Event #1, 2018 Tbili-60% Chloride (Cl) Testing event #1, 2017 Cl-20% Testing Event #3, 2017 Cl-40% Testing Event #1, 2018 Cl-40%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the subspecialty of routine chemistry Findings include: On August 29, 2018, on or about 10:00 AM, the American Proficiency Institute (API) and the American Society of Internal Medicine (MLE) proficiency testing records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had subsequent unsatisfactory proficiency testing score for the analytes, total bilirubin and chloride, in the subspecialty of routine chemistry. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D 2096.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing for the analytes total bilirubin and chloride both of which are in the subspecialty of routine chemistry. Findings Include: On August 29, 2018, on or about 10:00 AM, the American Proficiency Institute (API) and the American Society of Internal Medicine (MLE) proficiency testing records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the the laboratory had subsequent unsuccessful performance in proficiency testing for the analytes total bilirubin (Tbili) and chloride (Cl) as shown below. Total bilirubin (Tbili) Testing event #1, 2017 Tbili-40% Testing Event #3, 2017 Tbili-0% Testing Event #1, 2018 Tbili-60% Chloride (Cl) Testing event #1, 2017 Cl-20% Testing Event #3, 2017 Cl-40% Testing Event #1, 2018 Cl-40%.